

# **Recommendations for the Use of Mycobacterium Direct Testing as Performed by the Washington State Public Health Laboratories.**

- 1. One form of Nucleic Acid Amplification (NAA) technique used to detect and identify *Mycobacterium tuberculosis* complex directly from clinical respiratory specimens is the Gen-Probe Amplified Mycobacterium Tuberculosis Direct Test (abbreviated as AMTD or MTD).**
- 2. Each initial sample for those patients highly suspected to have tuberculosis based on smear positive results or clinical suspicion should be given priority. The overall sensitivity for respiratory specimens is adequate and has been shown to range from 85.7% to 97.8% when compared to culture results – the gold standard for confirming TB infection. Smear positive specimens have a higher range of sensitivity (91.7% - 100%), while smear negative specimens show a drop in the sensitivity (65.5% - 92.9%).**
- 3. Highly suspected clinically active cases with smear negative results should be evaluated on a case-by-case basis. The specificity of amplification test is excellent (100%) and the CDC currently recommends that the test be performed on the first sputum sample collected from every patient, the American Thoracic Society workshop could not reach an agreement on the appropriate use of this test on smear negative patients and the use of this test on patients with low suspicion of pulmonary TB was not recommended.**
- 4. Suspect cases identified during an outbreak or as a cluster should also be given priority based on the need for timely test results even though the positive predictive and negative predictive value are unclear at this time.**

**Situations not recommended for routine MTD testing include:**

- 1. Those with previously known MTD results.**
- 2. Those with low clinical suspicion for *M. tuberculosis* infection/disease.**
- 3. Those with previously known *M. tuberculosis* infection/disease.**
- 4. Those patients on anti-tuberculosis drugs for more than 7 days or within the past 12 months**

**Any exceptions to these guidelines will trigger a discussion between the ordering physician and the state DOH TB medical consultant or Seattle-King County tuberculosis physicians for clinical approval.**